UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

United States of America and State of California, *ex rel.* Steven Higgins,

Plaintiffs,

v.

Boston Scientific Corporation,

Defendant.

Case No. 11-cv-2453 (JNE/TNL)

ORDER

I. INTRODUCTION

This matter is before the Court, United States Magistrate Judge Tony N. Leung, on Defendant's Motion to Strike and Exclude the Testimony of Lawrence Mayer (ECF No. 404). For the reasons outlined below, the Court grants Defendant's motion.

II. BACKGROUND

By way of brief background, Relator Steven Higgins, MD, initiated this *qui tam* action on August 26, 2011 on behalf of the United States and the State of California under the False Claims Act and the California False Claims Act. (Compl. ¶ 1, ECF No. 1.) Relator alleged that Defendant engaged in two distinct schemes: (1) selling defective cardiac defibrillator devices under the names Cognis and Teligen ("C/T Devices"); and (2) providing kickbacks. (Compl. ¶ 2.) Almost five years later, the United States and the State of California declined to intervene, and, on May 6, 2016, Relator was permitted to pursue this action on their behalf. (ECF Nos. 44, 47.) Relator thereafter filed his Amended Complaint on October 7, 2016. (Am. Compl., ECF No. 61.)

In the operative Second Amended Complaint, Relator alleges that Defendant has engaged in a fraudulent scheme whereby it sought Food and Drug Administration ("FDA") approval and subsequently sold Version 1 of C/T Devices, which were defective. (Second Am. Compl., ECF No. 98.) This includes the allegation that Version 1 of the C/T Devices suffered from "serious, fatal defects in the design of their set screws, seal plugs, and header" and that "[t]hese defects were inherent in all of the devices." (*Id.* ¶ 3; *see also id.* ¶¶ 273-75.) In 2008, Defendant implemented a design change in the C/T Devices. (*Id.* ¶¶ 155-57.) This "Version 2" of the C/T Devices was released in 2009. (*Id.* ¶¶ 155-60.)

III. MOTION TO STRIKE

Relator has produced a rebuttal report by Dr. Lawrence Mayer and argues that it is in response to the opinion presented by Defendant's medical expert, Dr. Kenneth Ellenbogen. Defendant argues Dr. Mayer's opinion and expert report do not rebut the opinion of Dr. Ellenbogen; rather, Defendant argues this testimony is a "repackaged" affirmative opinion that Relator seeks to use in his case in chief. (Def.'s Mem. in Supp. at 2, ECF No. 407.) Defendant asks the Court to strike this expert report and exclude Dr. Mayer's testimony at trial pursuant to Federal Rules of Civil Procedure 26 and 37, or, in the alternative, to allow Defendant to designate a rebuttal expert to respond to Dr. Mayer's opinions. (*Id.* at 14.) Relator responds that Dr. Mayer's report is permissible rebuttal testimony and opposes Defendant's request for an additional expert to rebut Dr. Mayer, arguing that Defendant has long been aware of Relator's intention to use Dr. Mayer as a rebuttal expert and Defendant's request for an additional expert to rebut his testimony

amounts to an improper motion to modify the Court's scheduling order. (*See generally* Relator's Mem. in Opp'n, ECF No. 416.)

A. Relevant Background

On October 8, 2019, Relator filed a motion to substitute one of his four experts for Dr. Mayer. (*See* ECF No. 301.) At that time, the operative pretrial scheduling order was the Third Amended Pretrial Scheduling Order, which set August 31, 2019 as the deadline for identifying expert witnesses. (ECF No. 278 at 1-2.) The Court denied Relator's motion to substitute Dr. Mayer as an expert on the basis that Relator was not diligent in trying to meet the disclosure deadline. (ECF No. 321 at 2-3.) In this order, the Court explicitly declined to rule on the question of whether Dr. Mayer could serve as a rebuttal expert, stating:

> Because Relator has de-designated Ulricks as an expert he now has one open expert witness slot to use for a rebuttal expert, be that Dr. Mayer or someone else. The parties both improperly ask the Court to weigh in on whether Dr. Mayer is an appropriate rebuttal expert witness. There is no basis for the Court, at this time, to prevent Dr. Mayer from being identified as Relator's rebuttal expert witness. The Court will not provide the parties with an anticipatory or advisory ruling on testimony that has not yet been generated in response to expert reports that have not been provided.

(*Id.* at 3.)

B. Analysis

"[T]he purpose of our modern discovery procedure is to narrow the issues, to eliminate surprise, and to achieve substantial justice." *Mawby v. United States*, 999 F.2d 1252, 1254 (8th Cir. 1993) (citation omitted). "A party must disclose expert opinions 'at

the times and in the sequence that the court orders.'" *United States v. STABL, Inc.*, 800 F.3d 476, 487 (8th Cir. 2015) (quoting Fed. R. Civ. P. 26(a)(2)(D)). Under Rule 26(a)(2)(A), "a party must disclose to the other parties the identity of any witness it may use at trial to present evidence under Federal Rule of Evidence 702, 703, or 705;" *see also, e.g.*, *Vanderberg v. Petco Animal Supplies Stores, Inc.*, 906 F.3d 698, 702 (8th Cir. 2018) (outlining the disclosure requirements for expert witnesses under Rule 26 and concluding that "[t]he disclosure mandates in Rule 26 are given teeth by the threat of sanctions in Rule 37.").

"The function of rebuttal testimony is to explain, repel, counteract or disprove evidence of the adverse party." *Marmo v. Tyson Fresh Meats, Inc.*, 457 F.3d 748, 759 (8th Cir. 2006) (quoting *United States v. Lamoreaux*, 422 F.3d 750, 755 (8th Cir. 2005)); *cf.* Fed. R. Civ. P. 26(a)(2)(C) (rebuttal experts allowed solely to "contradict or rebut evidence on the same subject matter identified by another party"). "As such, rebuttal evidence may be used to challenge the evidence or theory of an opponent—and not to establish a case-in-chief." *Marmo*, 457 F.3d at 759 (citing *Cates v. Sears, Roebuck & Co.*, 928 F.2d 679, 685 (5th Cir. 1991)).

Relator argues that Defendant "knew no later than October 24, 2019 that Relator sought to offer Dr. Mayer to testify regarding the differences in mortality between Version 1 and Version 2" of the C/T Devices. (Relator's Mem. in Opp'n at 2.) Relator further contends that the "extraordinarily broad opinions about the purported safety and effectiveness of" the C/T Devices in Dr. Ellenbogen's report opened the door to allowing Dr. Mayer's findings to be used in a rebuttal report. (*Id.* at 20.)

The Court is unconvinced by this argument and must instead ask whether Dr. Mayer's testimony was offered "solely to contradict or rebut evidence on the same subject matter." Fed. R. Civ. P. 26(a)(2)(B); *see also Marmo*, 457 F.3d at 759. In comparing the two reports, the Court finds that Dr. Mayer's report does not rebut Dr. Ellenbogen's report and is instead an affirmative opinion on the relative safety between the two versions of the C/T Devices.

1. The Ellenbogen Report

According to his report, Dr. Ellenbogen is a medical doctor and practicing physician from Virginia who is "familiar with the standard of care for the selection, implantation and management of patients with implanted pacemakers and defibrillators." (Ex. E to Def.'s Mem. in Supp. of Mot. (hereinafter "Ellenbogen Rpt.") at 1-2, ECF No. 408-5.) He has implanted Version 1 of the C/T Devices. (*Id.* at 2-3.) In the Summary of Opinions section of his report, Dr. Ellenbogen concluded that "Version 1 of the Devices was safe and effective and provided life-saving therapy to patients." (*Id.* at 4.)

Dr. Ellenbogen specified that he has implanted Version 1 of the C/T Devices, followed additional patients implanted with Version 1 of the C/T Devices, and referred yet additional patients implanted with the same devices to other physicians for care. (*Id.* at 5.) His report describes how the C/T Devices look and operate, and how they are implanted in patients. (*Id.* at 5-7.) Dr. Ellenbogen then compares the C/T Devices to previous devices manufactured by Defendant. (*Id.* at 7.)

Dr. Ellenbogen then opines that "Implantation of the [C/T Devices] including Version 1 of the Devices showed they were safe and effective devices that provide life-

saving therapy to patients provided that the patients' physician followed proper implantation techniques." (*Id.* at 8.) He further states that it is his belief that the header-setscrew connection issues with the C/T Devices could have been caused by physicians who "may have failed to follow proper implantation technique." (*Id.*) He asserts that, based on his personal experience implanting Version 1 of the C/T Devices he "has never had any significant concerns about header-setscrew connection issues" and that he has never heard any concerns from other implanting electrophysiologists in his "extensive" interactions with "hundreds" of physicians. (*Id.* at 9.) He notes that during the time that Version 1 of the C/T Devices was marketed that there were similar adverse issues related to the header-setscrew connection with "at least one other device manufactured by [Defendant's] competitors and that "[i]ndeed, header-setscrew connection issues have been present since the development of pacemakers and defibrillators, and still continue to this day to be a rare issue." (*Id.*)

While Dr. Ellenbogen did not implant Version 2 of the C/T Devices, he states that it is common for medical device manufacturers to update or enhance their devices, that physicians would not view a design of a new version (in this case, Version 2) as an indication that Version 1 of the C/T Devices was unsafe or ineffective, and that "physicians would not have expected [Defendant] to cease sales of Version 1 while Version 2 was being designed and approved by the FDA." (*Id.* at 11.) He also opines that Defendant's retrieval of Version 1 and the subsequent Class II recall by the FDA did not render Version 1 of the C/T Devices medically unnecessary or require physicians to perform replacement surgeries. (*Id.* at 11-12.) Dr. Ellenbogen concludes that Version 1 of the C/T Devices were

"safe and effective provided that the implanting physician followed proper implantation techniques. Moreover, to the extent a patient was implanted with a Device that experienced header-setscrew connection issues, the risk to the patient was exceedingly low and could be diagnosed quickly after implant." (*Id.* at 14.)

2. The Mayer Report

According to his report, Dr. Mayer is a research physician, epidemiologist, and biostatistician. (Ex. 4 to Relator's Mem. in Opp'n to Mot. (hereinafter "Mayer Rpt.") ¶ 3, ECF No. 417-4.) Dr. Mayer's report discusses "[a] statistical analysis and comparison of the mortality rates observed in patients who were implanted with Version 1 and Version 2" of the C/T Devices. (*Id.* ¶ 1.)

This statistical analysis led to the following opinions: first, that "[t]he mortality rate of patients who were implanted with a Version 1 Device was higher—to a very high degree of statistical certainty—than that of patients who were implanted with a Version 2 Device, even when controlling for patient gender and age;" and that the mortality rates for the two versions of the C/T Devices implanted in the Richmond, Virginia area (where Dr. Ellenbogen practices) are "similar to the respective nationwide mortality rates for those Devices, and there is insufficient data to conclude that patients who were implanted with Version 1 Devices in the Richmond, Virginia area had better or worse mortality outcomes than Version 1 patients nationwide." (*Id.* ¶ 2.)

Dr. Mayer, after discussing his qualifications, discusses the mortality rates between Version 1 and Version 2 of the C/T Devices (*Id.* at pp. 3-4.) These statistical results are attached in an appendix to Dr. Mayer's report. (*See id.* ¶ 18.) Dr. Mayer found when

analyzing the data that patients implanted with Version 1 of the C/T Devices and followed for 9 years had "a significantly higher mortality rate than those implanted with" Version 2 of the C/T Devices. (*Id.* ¶ 22.) Under this analysis, there were 805 deaths over the 9-year period attributable to the mortality risk difference, and a similar calculation based on the data set revealed that "on the average, 1 out of every 40 patients given Version 1 would have remained alive during the mortality window had they been given Version 2 instead." (*Id.* ¶¶ 22-23.) Dr. Mayer concludes in his report that "there is no doubt that the Version 1 of the Device is associated with an increase in mortality as compared to Version 2. The difference between the mortality of the two Devices is highly significant." (*Id.* ¶ 24.) Underneath this conclusion, Dr. Mayer states that he filtered the patient registry information to limit the same data set to patient outcomes in the Richmond area, where Dr. Ellenbogen practices, and determined that "there is insufficient evidence to conclude the mortality rates for patients implanted with a Version 1 or Version 2 Device in the Richmond area differ significantly from the mortality rates for all patients in the data set." (*Id.* ¶ 25.)

3. The Two Reports Compared

As discussed above, Dr. Ellenbogen's report concludes that, in his opinion, based on his training and experience, Version 1 of the C/T Devices was safe and effective. (*See generally* Ellenbogen Rpt.) This opinion was not affected by the updating of the product to Version 2, Defendant's retrieval of Version I, or the Class II recall of Version I by the FDA. (Ellenbogen Rpt. at 11.) Dr. Ellenbogen's report does not comment on the safety or effectiveness of Version 2 of the C/T Devices.

On the contrary, Dr. Mayer's report is a statistical analysis which *only* comments on the relative safety of the two versions of the C/T Devices as they relate to one another. (*See generally* Mayer Rpt.) Dr. Mayer's report claims nothing about the safety of Version 1 of the C/T Devices, except to state that there was a statistically significant difference in the mortality rates between the two versions of the C/T Devices. (*Id.* ¶¶ 22-24.) It does not respond to Dr. Ellenbogen's report except to say that his report was reviewed (*id.* ¶ 1) and that the same set of data was narrowed to consider the geographical area in which Dr. Ellenbogen practices. (*Id.* ¶¶ 2, 25.) Relator's assertion that because Dr. Ellenbogen makes a general argument about the effectiveness and safety of one version of the C/T Devices does not lead to the conclusion that any proffered expert testimony about safety or efficacy would be proper rebuttal. Instead, the Court looks to whether Dr. Mayer's report explains, repels, counteracts, or disproves evidence proffered by Dr. Ellenbogen, and determines it does not. *See Marmo*, 457 F.3d at 759.

This conclusion is borne out by the deposition taken of Dr. Mayer on December 1, 2020, where Dr. Mayer stated that he had originally been retained to run a statistical analysis comparing the mortality rates of the two versions:

> Q: Okay. So it's your understanding, when you were first retained in August 2019, that it was always - - the intention of your engagement was always to look to see if there was a statistical difference - - a statistically significant difference in the mortality rates for persons who got Version 1 of the device versus persons who got Version 2 of the device, is that correct?
>
> A: If I could change the device to the plural devices, yes, that would be correct.

(Ex. A to Def.'s Mem. in Supp. of Mot. ("Mayer Dep.") 19:5-14, ECF No. 408-1.) The transcript further reveals that Dr. Mayer initially ran this mortality analysis in the fall of 2019, and that the only difference between that statistical analysis and the one completed for his final rebuttal report was the size of the data set. (*Id.* 14:18- 15:6, 15:21-16:5, 18:11-19:4; *see also* Oct. 24, 2019 Ltr. to the Court from Relator at 2-3 (summarizing Dr. Mayer's planned affirmative testimony and stating that "Dr. Mayer's initial analysis posits that the survival rate for patients who received Version 1 devices was lower than the survival rate for patients who received Version 2 devices."), ECF No. 316.) Dr. Mayer also testified that his analysis "was to show that compared to Version 2, Version 1 was not safe and effective, in that it could be made equally effective and safer if it had been replaced by Version 2." (*Id.* 25:16-19; *see also id.* 44:2-15, 16-22 (testifying that in his opinion Version 1 was "less safe" statistically compared to Version 2 and that he believed there was "no reason to believe [Version 1 of the C/T Devices] was not effective.".)

Relator's attempt to shoehorn in Dr. Mayer's tardy statistical analysis comparing the mortality rates of the two versions of the C/T Devices by having him single out the data from the area where Dr. Ellenbogen practices does not mean that Dr. Mayer's report rebuts Dr. Ellenbogen's report. *See* Fed. R. Civ. P. 26(a)(2)(D)(ii) (outlining disclosures of expert testimony "if the evidence is intended solely to contradict or rebut evidence on the same subject matter identified by another party."); *see also In re Air Crash Near Kirksville, MO on Oct. 19, 2004*, No. 4:05MD1702 JCH, 2007 WL 2363505, at *3 (E.D. Mo. Aug. 16, 2007). Dr. Mayer's testimony is not proper rebuttal as it advances a theory (namely, that the comparative mortality rates of the two versions of the C/T Devices shows that Version

1 was unsafe) which is suited for Relator's case-in-chief and does not rebut Dr. Ellenbogen's testimony that Version 1 of the C/T Devices was safe and effective. *See in re Air Crash*, 2007 WL 2363505, at *3.

Relator missed the deadline for identifying Dr. Mayer as an affirmative expert witness; the Court denied Relator's motion to substitute Dr. Mayer for another affirmative expert witness; and the Court will not now permit Relator to style Dr. Mayer's report as rebuttal to get in by the backdoor what it could not get in through the front gate.

4. Sanctions

Under Rule 37(c)(1), "[i]f a party fails to provide information or identify a witness as required by Rule 26(a) or (e), the party is not allowed to use that information or witness to supply evidence on a motion, at a hearing, or at trial, unless the failure was substantially justified or is harmless;" *see also Wegener v. Johnson*, 527 F.3d 687, 692 (8th Cir. 2008) ("When a party fails to provide information or identify a witness in compliance with Rule 26 (a) or (e), the district court has wide discretion to fashion a remedy or sanction as appropriate for the particular circumstances of the case."). "[W]hen determining whether a violation was substantially justified or harmless under Rule 37(c), district courts consider four factors: '(1) the importance of the excluded material; (2) the explanation of the party for its failure to comply with the required disclosure; (3) the potential prejudice that would arise from allowing the material to be used . . . ; and (4) the availability of a continuance to cure such prejudice.'" *United States ex rel. Fesenmaier v. Cameron-Ehlen Grp., Inc.*, No. 13-cv-3003 (WMW/DTS), 2021 WL 101193, at *22 (quoting *Transclean Corp. v.*

Bridgewood Servs., Inc., 101 F. Supp. 2d 788, 795-96 (D. Minn. 2000)). "[T]he exclusion of evidence is a harsh penalty and should be used sparingly." *Wegener*, 527 F.3d at 692.

When considering these factors, the Court finds that excluding Dr. Mayer's testimony is warranted in this case because Relators failure to name Dr. Mayer at the appropriate deadline is not substantially justified or harmless. While the information contained in Dr. Mayer's report supports Relator's argument that Version 1 of the C/T Devices were unsafe and ineffective, Relator has designated two other affirmative expert witnesses who advance this opinion. Further, there would be great prejudice to Defendants, who do not have an expert to rebut the statistical analysis performed by Dr. Mayer.[1] Relator provides little explanation as to why he did not comply with the required disclosure deadline for an affirmative expert report, and instead maintains through much of his memorandum in opposition that Dr. Mayer's report is proper rebuttal testimony. (*See generally* Relator's Mem. in Opp'n.) As the Court has discussed at length, *supra* at Section III(B)(1)-(3), Dr. Mayer's report does not rebut Dr. Ellenbogen's report. The Court has previously found that Relator was not diligent in trying to meet the disclosure deadline. (*See* ECF No. 321 at 2-3.) In addition, the contentious history of this litigation and its late

[1] Relator's argument that Defendant has been on notice of his plan to use Dr. Mayer as a rebuttal expert since October 2019 is unavailing. (*See* Relator's Mem. in Opp'n at 19-20.) Relator did argue at the time he proposed substituting Dr. Mayer as an affirmative expert witness that Dr. Mayer's statistical analysis may rebut Dr. Ellenbogen's report. (*See* ECF No. 303 at 3 n.2; *see also* ECF No. 316 at 2 n.2.) Dr. Ellenbogen's report was not served, however, until August 31, 2020. (Relator's Mem. in Opp'n at 6.) Further, Dr. Mayer was not disclosed as a rebuttal expert to Dr. Ellenbogen until September 22, 2020 and Dr. Mayer's rebuttal report was not served until October 15, 2020. (*Id.* at 2.) Thus, Defendant could not review the full contents of the rebuttal report until October 15, 2020.

stage weigh against granting a continuance.[2] The Court will strike and exclude the testimony of Dr. Lawrence Mayer.

IV. ORDER

Therefore, based on the foregoing, **IT IS HEREBY ORDERED THAT**:

1. Defendant's Motion to Strike and Exclude the Testimony of Lawrence Mayer (ECF No. 404) is **GRANTED**.

2. All prior consistent orders remain in full force and effect.

3. Failure to comply with any provision of this Order or any other prior consistent Order shall subject the non-complying party, non-complying counsel and/or the party such counsel represents to any and all appropriate remedies, sanctions and the like, including without limitation: assessment of costs, fines and attorneys' fees and disbursements; waiver of rights to object; exclusion or limitation of witnesses, testimony, exhibits and other evidence; striking of pleadings; complete or partial dismissal with prejudice; entry of whole or partial default judgment; and/or any other relief that this Court may from time to time deem appropriate.

Date: April 27, 2021

s/Tony N. Leung
Tony N. Leung
United States Magistrate Judge
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[2] As the Court is granting Defendant's motion to strike Dr. Mayer's testimony, it does not reach the issue of whether Defendant has shown good cause to modify the scheduling order for the purpose of adding an additional expert to respond to Dr. Mayer's report.